Remarks

This Amendment is submitted in response to the office action mailed November 4, 2004, in connection with the above-identified application (hereinafter the "Office Action"). The Office Action provided a three-month shortened statutory period in which to respond, ending on February 4, 2005. Submitted herewith is a Petition for One Month Extension of Time, thus extending the deadline to March 4, 2005. Accordingly, this Amendment is timely submitted.

Claims 1-6, 8 and 12-31 are currently pending. Applicants respectfully request that claims 12 to 26 be cancelled without prejudice. Applicants reserve the right to prosecute these claims in a later to be filed application. Applicants also respectfully request entry of new claims 32 through 33. Moreover, Applicants respectfully request entry of the amendments to claims 1 and 27. Applicants respectfully submit that the new claims and amendments to pending claims do not introduce any new matter. Thus, claims 1 through 6; 8; and 12 through 31 are currently pending.

Withdrawal of Claims 27 through 31

The Examiner has stated that Claims 27 through 31 are withdrawn from consideration as being directed to a non-elected invention. Applicant's respectfully disagree with this conclusion, and wish to state that Claims 27 to 31 are consistent with the originally presented composition claims. Claims 27 to 31 relate to a process that may be used to result in the compositions disclosed in the originally presented claims.

The Examiner states that because polyvinyl alcohol is a water-soluble polymer, the resulting compositions of Claims 27 through 31 are soluble. Applicant's respectfully disagree. Applicants are claiming pharmaceutical composition for oral administration of an active agent having low water solubility, which compositions containing nanoparticles having the active may be adsorbed at their surface or entrapped in the polymeric matrix (i.e. pharmaceutically acceptable polymer). Upon administration of the oral dosage form, the active agent is released from the nanoparticles in pH-neutral or slightly basic juices present in the small intestine.

Claim 27 has been amended to specify the pharmaceutically acceptable polymers of the present invention which include (a) methacrylic acid or acrylic acid and (b) methyl or ethyl esters of acrylic or ethacrylic acid monomers, (ii) polyvinyl acetate phthalate (PVAP), (iii) hydroxypropyl methyl cellulose acetate succinate (HPMCAS), (iv) hydroxypropyl methyl cellulose phthalate (HPMCP), (v) cellulose acetate phthalate (CAP) and, (vi) cellulose acetate trimellitate (CAT).

The active agent is, thus released from the polymers mentioned in the prior paragraph, not necessarily polyvinyl alcohol. Because of the nature of the pharmaceutically acceptable

polymers, the compositions produced by Claims 27 through 31 are thus not soluble in gastric juices and are consistent with the originally presented compositions.

Applicants respectfully request that the Examiner reconsider the need for Claims 27 through 31 to be withdrawn.

Rejection under 35 U.S.C. § 102

Claims 1-3, 8, 12-15, 23-26 are rejected under 36 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,343,789 to Kawata et al (hereinafter, "*Kawata*"). The Examiner states that *Kawata* discloses fine powders of active agents of low solubility coated with various copolymers of met acrylic acid and met acrylic esters or hydroxpropylmethyl cellulose phthalates. The Examiner also notes that the fine powders are pulverized for sixteen hours in a vibrating ball mill.

Applicants respectfully disagree with this rejection. Claim 1 expressly sets forth that "the active agent is dispersed in an aqueous formulation base." *Kawata* fails to teach this limitation. In the examiners in which the fine powders are pulverized for sixteen hours in a vibrating ball mill (Examples 5, 6, 7, and 8). In each of these examples the active agent was mixed with a dry excipient and then subjected to pulverization by a vibrating ball mill. There is no disclosure or mention of the use of water. It appears that the use of the vibrating ball mill is for the conversion of a crystalline active agent to an amorphous form (as suggested by dependent claims 4 and 5 of *Kawata*).

Although Example 9 mentions water, Claim 1 is distinguishable, because the active agent is sprayed with a solution of 10 g of methyl cellulose in 1000 g of water. In contrast, Claim 1 requires that the active agent is dispersed in an aqueous formulation base.

Furthermore, Claim 1 expressly sets forth that the nanoparticles are in an aqueous dispersion. None of the Examples in *Kawata* using a vibrating ball mill teach or suggest nanoparticles in an aqueous dispersion.

Thus, Applicants respectfully submit that this rejection is overcome.

Rejection under 35 U.S.C. § 103(a)

Claims 1-6, 8 and 12 through 26 are rejected under 35 U.S.C. § 103(a) as being unpatentable over *Kawata* or Stainmesse et al. (hereinafter "*Stainmesse*").

Claim 1 has been amended to recite the limitation of requiring the aqueous formulation base to further contain a hydrophilic polymer. *Kawata* is silent regarding the inclusion of polyvinyl alcohol. First, as discussed above, *Kawata* does not teach or suggest an active agent

dispersed in an aqueous formulation base. Second, the fact that the aqueous formulation base further contains polyvinyl alcohol is nowhere mentioned in *Kawata*.

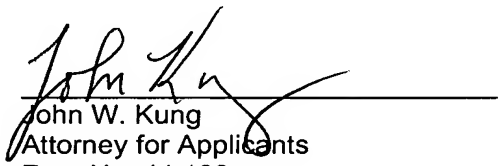
Such a deficiency in *Kawata* is not cured by the combination of Stainmesse. *Stainmesse* fails to teach or suggest the use of polyvinyl alcohol in the aqueous formulation base.

Because *Kawata* and *Stainmesse*, individually and/or combined, failed to teach each and every limitation of Claim 1, the rejection under 35 U.S.C. § 103(a) is improper. Thus, Applicants respectfully submit that this rejection be withdrawn.

Applicants also wish to note that references that in the previous Office Action mailed April 7, 2004, a rejection under 35 U.S.C. § 103(a) combining *Stainmesse* with *Preparation of aqueous polymeric nanodispersions by a reversible salting-out process: influence of process parameters on particle size* to Allémann et al. (hereinafter "*Allémann*") or U.S. Patent No. 4,968,350 to Bindschaedler et al. (hereinafter "*Bindschaedler*"). Applicants respectfully submit that the herein amended Claim 1 is not obvious in view of Stainmesse combined with *Allémann* and/or *Bindschaedler* for the same reasons stated in the Applicant's response of July 2, 2004.

Thus, in view of the foregoing arguments, Applicants respectfully request reconsideration of the present application. If a telephone interview would be of assistance in advancing the prosecution of this application, Applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

Respectfully submitted,



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